REMARKS

I. Status of the Application

Claims 1-3 and 5-24 are presently pending in the application. New claims 25 and 26 have been added. Applicant gratefully acknowledges that the terminal disclaimer filed on July 22, 2004 has been accepted by the Examiner. Claims 1-3 and 5-24 remain rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. Claims 1-3 and 5-24 remain rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 1-3, 7-9, 13, 14, 17, 20 and 22 remain rejected under 35 U.S.C. §102(b) or 35 U.S.C. §103(a) as anticipated by or obvious over Antelman, U.S. Patent No. 5,571,520. Claims 1-3 and 5-24 remain rejected under 35 U.S.C. §103(a) as obvious over Antelman, U.S. Patent No. 5,571,520, in view of De Cuellar et al., U.S. Patent No. 4,828,832, Fox Jr. et al., U.S. Patent No. 5,334,588, Dorland's (28th Ed. 1994), The Merck Manual (16th Ed. 1992), and Remington's (17th Ed. 1985).

Applicant has amended the claims to more clearly define and distinctly characterize Applicant's novel invention. The amendments to the claims can be found in the specification and the claims as originally filed. Support for the amendments to claims 1 and 8 to recite a "semi-solid or solid" carrier medium can be found in the specification at least at page 12, lines 24-27, where Applicant teaches tetrasilver tetroxide compositions including "semi-solid or solid forms". Claim 22 was amended to address formal matters. Support for new claims 25 and 26 can be found in the specification at least at page 6, line 31, where Applicant teaches non-pathogenic, dermatological skin conditions; page 6, lines 13-18, where Applicant teaches preventing, treating or managing eczema, psoriasis, dermatitis, heat rash, skin ulcer, bedsore, blister, boil, skin chafing, skin cracking, skin itch and skin peeling; and at page 5, line 15, where Applicant teaches pharmaceutical compositions. The amendments presented herein add no new matter. Applicant respectfully requests entry and

consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

II. Formal Matters

At the outset, Applicant respectfully submits that the instant Final Office Action incorrectly lists the correspondence address as Perry Antelman, Marantech Holding LLC, One Turk's Head Place, Suite 810, Providence, RI 01903. Applicant submits that a Revocation of Power of Attorney changing the correspondence in the above-referenced application to John P. Iwanicki, Banner & Witcoff, Ltd. 28 State Street, 28th Floor, Boston, MA 02109, was filed with the Amendment and Response mailed by Applicant on July 22, 2004. A copy of the Revocation of Power of Attorney is provided herewith. Accordingly, Applicant respectfully request that all future correspondence be directed to John P. Iwanicki at the above address.

III. Claims 1-3 and 5-24 Are Enabled

At page 2, paragraph 4 of the instant Office Action, claims 1-3 and 5-24 remain rejected under 35 U.S.C. §112, first paragraph, because the Examiner asserts that the specification, while being enabling for tetrasilver tetroxide, does not reasonably provide enablement for all pharmaceutically acceptable derivatives or treatment, prevention or management of all conditions. The Examiner is of the opinion that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant respectfully traverses this rejection.

Without acquiescing to the rejection, Applicant respectfully submits that the claims have been amended to remove the language "or a pharmaceutically acceptable derivative thereof" solely to

expedite prosecution. With respect to the Examiner's assertion that the specification does not provide enabling disclosure for the treatment, prevention or management of all dermatological skin conditions, Applicants respectfully disagree.

The proper standard by which to evaluate the scope of enablement that the specification provides for claims 1-3 and 5-24 is whether any experimentation that may be needed to practice the claimed invention by the skilled artisan is undue or unreasonable. *In re Wands*, 858 F.2d 731, 736-37, 8 U.S.P.Q.2d (BNA) 1400, 1404 (Fed. Cir. 1988). The legal test for whether a disclosure provides adequate enablement for a generic claim is that "the scope of the claims must bear a *reasonable correlation* to the scope of enablement provided by the specification to persons of ordinary skill in the art." *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. (BNA) 18, 24 (C.C.P.A. 1970) (emphasis added). The present specification meets this standard and therefore enables the claimed composition and method for preventing, treating or managing one or more dermatological skin conditions or diseases.

The specification is addressed to those skilled in the art. The law is clear that the specification need not provide knowledge which is generally known by those skilled in the art; Applicant can properly rely on common knowledge in the art to bolster and supplement his disclosure. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986); *Genentech Inc. v. Novo Nordisk A/S*, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997). The teachings in the specification, together with the knowledge and skill of those in the art at the time of filing, would guide one skilled in the art as to the prevention, treatment or management of dermatological skin conditions or diseases. One of skill in the art, at the time of filing, would readily understand whether tetrasilver tetroxide would be effective in preventing, treating or managing one or more dermatological skin conditions or diseases.

The Examiner asserts that Applicant provides "relatively few examples of effective treatment of a few dermatological conditions with tetrasilver tetroxide." Applicant respectfully disagrees. Applicant provides ***twelve*** working examples illustrating the treatment, prevention or management of a ***variety*** of dermatological skin diseases or disorders ranging from ***viral*** (e.g., herpes in Examples 3, 5, 6 and 8) to ***bacterial*** (e.g., acne in Example 7) to ***fungal*** (e.g., Examples 2 and 12) to ***non-pathogenic*** (e.g., vaginal itch in Example 4, foot ulcers in Example 9, atopic dermatitis in Example 10, and psoriasis in Example 11) to ***diseases of unknown etiology*** (e.g., unknown tropical disease in Example 1). Whether tetrasilver tetroxide is effective for the treating, preventing or managing one or more dermatological skin diseases or conditions could easily be determined merely by carrying out routine screening using the assays disclosed in Applicant's twelve working examples. It would be obvious to one of skill in the art based on Applicant's teachings, for example, to determine pharmaceutical efficacy by merely visually observing whether a condition is treated, prevented or managed by tetrasilver tetroxide. Other assays of determining the status of viral infections, bacterial infections, fungal infections, non-pathogenic disorders and the like are well known in the art and would be readily achievable by one of skill in the art. For example, a variety of assays including biopsies, blood chemistry screens or immunological assays could be used to determine the pharmaceutical efficacy of tetrasilver tetroxide.

Accordingly, Applicant's specification, coupled with the level of skill in the art, enables a person of skill in the art to make and/or use the claimed invention without recourse to undue experimentation. Therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-3 and 5-24 under 35 U.S.C. § 112, first paragraph.

IV. Claims 1-3 and 5-24 Are Definite

At page 4, paragraph 3 of the instant Office Action, claims 1-3 and 5-24 remain rejected under 35 U.S.C. §112, second paragraph as being indefinite. The Examiner is of the opinion that the specification discloses the use of pharmaceutically acceptable salts of tetrasilver tetroxide. The Examiner asserts, however, that Applicant has made no showing that a pharmaceutically acceptable derivative is limited to salts of tetrasilver tetroxide and that, as such, there is still the issue as to what is and what is not included within the scope of the term "pharmaceutically acceptable derivative". Applicant respectfully traverses this rejection.

Without acquiescing to the rejection, Applicant respectfully submits that the claims have been amended to remove the language "or a pharmaceutically acceptable derivative thereof" in order to expedite prosecution. Accordingly, Applicant respectfully requests that the rejection of claims 1-3 and 5-24 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

V. The Pending Claims Are Novel And Nonobvious Over the Cited Art

At page 6, paragraph 2 of the instant Office Action, claims 1-3, 7-9, 13, 14, 17, 20 and 22 remain rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Antelman, U.S. Patent No. 5,571,520. The Examiner is of the opinion that the Antelman reference expressly discloses a method of treating athlete's foot and toenail fungus with solutions of tetrasilver tetroxide falling within the scope of Applicant's claims. The Examiner asserts that in the alternative, the claimed invention is rendered obvious because the cited art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. The Examiner further asserts that Applicant has provided no evidence that the

amounts of persulfate added in the other examples cited by Applicant are greater than about 10% of said examples.

At page 7, paragraph 1 of the instant Office Action, claims 1-3 and 5-24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Antelman reference in view of De Cuellar et al., U.S. Patent No. 4,828,832, Fox Jr. et al., U.S. Patent No. 5,334,588, Dorland's, 28th Ed. (1994), The Merck Manual, 16th Ed. (1992), and Remington's, 17th Ed. (1985). The Examiner asserts that the prior art rejection as a whole discloses the use of tetrasilver tetroxide without the use of added persulfate. Applicant respectfully traverses these rejections based on the amended claims presented herein.

Amended claim 1 and claims depending therefrom are directed to a pharmaceutical composition for preventing, treating or managing one or more dermatological skin conditions comprising a therapeutically effective amount of tetrasilver tetroxide substantially free of added persulfate, wherein the pharmaceutical composition further comprises a ***semi-solid or solid carrier medium*** that adheres to skin. Amended claim 8 and claims depending therefrom are directed to a method for preventing, treating, or managing one or more dermatological skin diseases in a patient's skin, which comprises administering tetrasilver tetroxide which is substantially free of added persulfate, to the skin in an amount and for a period of time which is therapeutically effective to treat such condition(s), wherein the pharmaceutical composition comprises a ***semi-solid or solid carrier medium*** that adheres to skin. Amended claim 23 and claims depending therefrom are directed to methods for preventing, treating, or managing one or more ***non-pathogenic***, dermatological skin conditions, which comprises administering tetrasilver tetroxide substantially free of added persulfate, to the skin in an amount and for a period of time which is therapeutically effective to treat such condition(s).

Antelman fails to teach or suggest a pharmaceutical composition comprising tetrasilver tetroxide ***substantially free of added persulfate***, and comprising a ***semi-solid or solid carrier medium that adheres to the skin***, as required by claims 1, 8 and claims depending therefrom. Instead, Antelman teaches that "oxidizing agents, particularly persulfates, enhance the efficacy" of their compositions (column 2, lines 33-34). This underscores the conventional knowledge in the art at the time the Antelman patent was filed that oxidizing agents should be added to silver tetroxide compositions to render the compositions effective for treating disorders such as bacterial, viral and algal infections. In fact, ***each example*** of topical use ***via a semi-solid carrier medium*** taught by Antelman ***includes high concentrations of sodium persulfate*** (Examples 1 and 2). Indeed, Examples 1 and 2 teach sodium persulfate levels that are *four to ten times* the levels of tetrasilver tetroxide present in the preparations. In contrast to Antelman, Applicant's claimed pharmaceutical composition comprising a semi-solid carrier medium is substantially free of added persulfate yet is still efficacious.

Applicant has also surprisingly discovered that tetrasilver tetroxide substantially free of added persulfate is effective for treating ***non-pathogenic*** dermatological skin disorders. The Antelman patent fails to teach or suggest Applicant's claimed method for preventing, treating, or managing one or more ***non-pathogenic***, dermatological skin conditions with a composition substantially free of added persulfate as required by claim 23 and claims depending therefrom. Claims 24 and 25 recite specific non-pathological skin conditions: eczema, psoriasis, dermatitis, heat rash and skin ulcer. In contrast to the claimed invention, Antelman is directed to "bactericidal, fungicidal and algicidal devices" (column 1, lines 11-13) and teaches topical treatment of the following ***pathogenic*** organisms: the ***bacteria*** *Staphylococcus* (Example 1); the ***yeast*** *Candida* (Example 2); athlete's foot

(Example 6), which is caused by a ***fungus***; and a ***fungus*** associated with toenail infection (Example 7). Nowhere does Antelman discuss the suitability of tetrasilver tetroxide for treating a non-pathogenic, dermatological skin condition, and based on the teachings of Antelman, one of skill in the art would have no reason to believe that tetrasilver tetroxide could have such a use.

The secondary references fail to cure the deficiencies of the Antelman patent. De Cuellar et al. is directed to the treatment of skin lesions, particularly burns, using compositions comprising metallic silver particles. De Cuellar et al. neither teaches nor suggests the claimed method or pharmaceutical composition comprising tetrasilver tetroxide substantially free of added persulfate. Instead, De Cuellar et al. teaches the ***inclusion*** of an ***oxidizing agent*** in their compositions "to cause the oxidation of the metallic silver particles and to produce oxygen to kill anaerobic bacteria" because "is believed that upon oxidation, the silver particles generate silver oxide ions" which "are a known antiseptic and germicide and kill the microbes which infect the legion" (column 3, lines 3-8). Furthermore, De Cuellar et al. teaches that their compositions should contain oxidizing agent at a concentration of at least 1% by weight (column 3, lines 11-14). Thus, De Cuellar et al. teaches inclusion of an oxidizing agent in their metallic silver compositions and fails to teach or suggest compositions that are substantially free of added oxidizing agent in general, let alone substantially free of added persulfate in particular, as claimed by Applicant.

Fox Jr. et al. is directed to antiviral compositions comprising a combination of silver salts and biguanides (column 3, lines 23-32). Fox Jr. et al. neither teaches nor suggests tetrasilver tetroxide substantially free of added persulfate, as claimed by Applicant.

Dorland's teaches that cold sores are caused by herpes simplex virus type I and that shingles is caused by herpes zoster (Office Action, page 7, last paragraph). Dorland's neither teaches nor suggests tetrasilver tetroxide substantially free of added persulfate, as claimed by Applicant.

The Merck Manual teaches that warts are caused by viruses (Office Action, page 8, first paragraph). The Merck Manual neither teaches nor suggests tetrasilver tetroxide substantially free of added persulfate, as claimed by Applicant.

Remington's teaches various combinations of drugs and bases. Remington's neither teaches nor suggests tetrasilver tetroxide substantially free of added persulfate, as claimed by Applicant.

Thus, the Antelman reference, alone or in combination with the secondary references, fails to teach or suggest all of Applicant's claim limitations. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of claims 1-3 and 5-24 under 35 U.S.C. §103(a) as obvious over Antelman, U.S. Patent No. 5,571,520, in view of De Cuellar et al., U.S. Patent No. 4,828,832, Fox Jr. et al., U.S. Patent No. 5,334,588, Dorland's, 28th Ed. (1994), The Merck Manual, 16th Ed. (1992), and Remington's, 17th Ed. (1985).

VII. Conclusion

Having addressed all outstanding issues, Applicant respectfully requests reconsideration and allowance of all pending claims. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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